UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,380	07/29/2003	Kirk Edward Vandezande	101384-22	6539

27388 7590 07/31/2006

NORRIS, MCLAUGHLIN & MARCUS
875 THIRD AVE
18TH FLOOR
NEW YORK, NY 10022

EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,380	VANDEZANDE, KIRK EDWARD	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *15-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 11-14* is/are rejected.

7)☒ Claim(s) *1-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/29/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Amendments

1. Applicant's election, with traverse, of Group I (claims 1-14) in the response filed 5/12/06 is acknowledged. The traversal is on the ground that the examiner has not cited patents to show different status of the inventions, and that since the classifications of the two inventions are the same, the restriction is not proper. This is not found persuasive because, as set forth in the previous Office action, while the methods are related and share some steps, they comprise distinct steps with regard to treating the received data, and produce distinct results. Group I involves a critical step of treating the received data with at least one decision tree algorithm, which generates strategies from the accessed records and calculates projected cost for the strategies. The result of the method is to score at least a portion of the new data received with the decision tree algorithm and generate a recommendation if the score satisfies a threshold. Group II, however, involves treating the received data by applying a match pattern to the history database created, which match pattern compares the match pattern to each of the accessed records, and calculates the frequency value from the matched records identified by the comparing step. The result of the method is to calculate the frequency value from the matched records identified by the comparing step, and generate a recommendation if a frequency value of matched records located by the match pattern satisfies a match threshold. The step of applying a decision tree algorithm in group I is distinct from that of applying a match pattern in group II because the two methods are known to be distinct bioinformatics method with distinct mathematical bases. Clearly the methods of group I and II are do not overlap in scope, not obvious variants and have different modes of actions, functions and/or effects. As such, searing

both groups together would involve searching all the distinct subject matter including decision tree algorithm and match pattern methods. Thus, the two inventions have distinct search fields. Decision tree algorithms and cost have to be searched for group I, which are not required for group II, and match pattern modeling has to be searched for group II, which is not required for group I, indicating that the searches for the two groups are not coextensive. Thus, there would be a serious search burden if they were examined together. Therefore, while the classifications of the two groups are the same, since the field of search for the two inventions are different, restriction for examination purposes as indicated is proper. See MPEP 808.02(R-3) (C).

The requirement is still deemed proper and is therefore made FINAL.

Accordingly, claims 1-18 are currently pending, claims 1-14 are under examination, and claims 15-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 5/12/06.

Information Disclosure Statement

2. The Information Disclosure Statement filed 7/29/03 has been entered and references therein have been considered. Initialed copies of the form PTO-1449 are enclosed with this action.

Specification

3. The specification is objected to because of the following:

It is noted that an Office letter was mailed on 10/27/03 requiring a substitute specification in compliance with 37 CFR 1.52, 1.121(b)(3) and 1.125. In response, applicant filed a substitute

specification on 12/23/03. However, the substitute specification filed is not in compliance with 37 CFR 1.52, 1.121(b)(3) and 1.125. Firstly, 37 CFR 1.121(b)(3) requires that a substitute specification be filed "by submitting an instruction to replace the specification." The response filed 12/23/03 does not include such instruction. Secondly, 37 CFR 1.125(b) requires that a substitute specification may be filed "if it is accompanied by a statement that the substitute specification includes no new matter." The response filed 12/23/03 does not include such statement. As such, a substitute specification in complete compliance with 37 CFR 1.52, 1.121(b)(3) and 1.125 is still required.

This Office action is based on the specification originally filed 7/29/03.

The title of the invention is not descriptive. The elected invention is drawn to a method and system for determining optimal test order for diagnosing mutations relating to a disease. The current title, however, is "Hierarchical Optimization for Procedural Effectiveness." A new title is required that is clearly indicative of the invention to which the elected claims are directed.

It appears that trademarks are used in this application, such as the OPENGENE on page 36. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

The brief description section of the specification on page 8 includes only a title phrase for Fig. 1, "HOPE for Unknown Unilateral Mutations." Since the drawing comprises convoluted symbols, non-English letters, etc., more description is needed.

The specification throughout uses the phrase "to diagnosis the disease." The word "diagnosis" is used in the English language as a noun only. It is suggested that the verb "diagnose" be used instead.

Appropriate correction is required.

Claim Objections

4. Claims 7-10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Claim 7, a multiple dependent claim, depends from claim 6, which is also a multiple dependent claim. Claims 8-10 directly or indirectly depend from claim 7. Accordingly, the claims have not been further treated on the merits.

Claims 1, 6 and 12 are objected to as containing the phrase "to diagnosis the disease." The word "diagnosis" is used in the English language as a noun only. It is suggested that the verb "diagnose" be used instead.

Claim 11 is objected to because it depends from itself.

Claim Rejections-35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-6 and 11-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a process or a computer readable medium comprising computer executable instructions to perform the process for determining an optimal test order. The process comprises receiving data, creating a database, receiving new data, applying a decision tree algorithm and generating a recommendation.

The following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm, a copy of which is enclosed herein).

The Guidelines states:

> *To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):*
>
> *- The claimed invention "transforms" an article or physical object to a different state or thing.*
> *- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.*

In the instant case, the claimed invention is a process of manipulating and converting data that does not transform an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Specifically it does not produce a tangible and useful result. While the last step of the process generates a recommendation, it does not include particular substance. Since it is not clear as to what the recommendation is about, such a process appears to be an abstract idea rather than a practical application of the idea because it does not produce a tangible result. Additionally, the

preambles of the claims, e.g. of claim 1, recite "determining an optimal test order for diagnosing mutations that relate to a disease" whereas the method steps repeatedly recite "diagnosis [sic] the diseases." Diagnosing mutations would be to determine the specifics of the mutations, e.g. a deletion, an insertion or a particular point mutation, whereas diagnosing a disease would be to determine the specifics of the diseases, e.g. a breast cancer, a long cancer or a heart disease. Thus, even if, assuming *arguendo*, that the recommendation were about test order, it would not be clear as to whether it would be for diagnosing mutations or diagnosing diseases. As to claims 4-6, even though the claimed system presents the optimal test order, it is not clear what tests are for. Therefore, the process or system also does not produce a useful result.

7. Claims 1-6 and 11-14 are rejected under 35 U.S.C. 101 also because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claims, as currently written, lack a patentable utility for the same reasons as set forth above, and in light of the indefiniteness of the claimed invention, as set forth below. While the preambles of the claims, e.g. that of claim 1, recite "determining an optimal test order for diagnosing mutations that relate to a disease," the method steps deal with data indicative of "assays required to diagnosis [sic] the diseases." Thus, it is not clear what the method/system is used for as also set forth above. Furthermore, the end result of the process in claims 1-3 and 12-14 is a "recommendation." It is not clear what the recommendation is about. Similarly, while the system of claims 4-6 presents "an optimal test order" determined based on input data, it is not clear what the test is for because it is not clear what the input data is about. As to claim 11, since

it depends from itself, it is not clear what the "system of claim 11" is and what it comprises. As a consequence, it is not clear what it can be used for.

Claim Rejections-35 USC § 112

8. The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-6 and 11-14 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention lacks a patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

10. The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-6 and 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preambles of the claims, e.g. that of claim 1, recite a method for determining the optimal test order for diagnosing mutations. However, the process steps do not produce such an optimal test order. While step e) of claim 1 generates "a recommendation," it is not clear what the recommendation is about. Furthermore, the preamble of claim 1 recites "determining an optimal test order for diagnosing mutations that relate to a disease" whereas the method steps

repeatedly recite "diagnosis [sic] the diseases." Diagnosing mutations would be to determine the specifics of the mutations, e.g. a deletion, an insertion or a particular point mutation whereas diagnosing a disease would be to determine the specifics of the diseases, e.g. a breast cancer, a long cancer or a heart disease. Thus, even if, assuming *arguendo*, that the recommendation were about test order, it would not be clear as to whether it would be for diagnosing mutations or diagnosing diseases.

Claim 2 recites in step d) "the at least one strategy identified by the comparing step." The phrase "the at least one strategy" lacks clear antecedent basis because neither claim 2 nor claim 1, from which claim 2 depends, recites "at least one strategy." And the "comparing" step of claim 2 does not produce "at least one strategy."

Claim 4 in item d) recites "at least a portion of the data." The phrase "the data" lacks clear antecedent basis. There are different types of data recited in items b) and c): the received data through the input device and the presented data through the output device. Thus, it is not clear as to what data is referred to in item d) by "the data": the received data or the presented data or both.

Claim 4 in item d) also recites "the at least one of the decision tree algorithms." The phrase "the decision tree algorithms" lack clear antecedent basis. The claim does not precedently recite plural "decision tree algorithms."

Claim 6 recites "the received data" in line 1. The phrase lacks clear antecedent basis because no received data is precedingly recited in the claim or in claim 4 or 5, from which claim 6 depends. Note that claim 4 only recite a device that is "for receiving data." No action of receiving data is recited.

Claim 11 depends from itself. Consequently, it is not clear what the "system of claim 11" is and what it comprises. Further, the phrases "the at least two strategies" and "the at least two medical diagnostic assays" lack antecedent basis.

Claim 13 recites in step d) "the at least one strategy identified by the comparing step." The phrase "the at least one strategy" lacks clear antecedent basis because neither claim 13 nor claim 12, from which claim 13 depends, recites "at least one strategy." And the "comparing" step of claim 13 does not produce "at least one strategy."

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 4-6 and 12-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bapat et al. (Gut, Vol 44, pages 698-703, 1999).

In light of the indefiniteness of the claims as set forth above, the art is being applied to the best interpretation and understanding of the claims as written.

Claims 12-14 are drawn to a process comprising computer executable instructions to perform the process for determining an optimal test order. The process comprises receiving data, creating a database, receiving new data, applying a decision tree algorithm and generating a recommendation.

Bapat et al. disclose a method for cost comparison of different strategies for screening and diagnosing familial adenomatous polyposis (FAP) using decision tree to determine the optimal test. Bapat et al. presented research data since 1991 including clinical testing of FAP and analysis of mutations of the gene APC that relate to FAP. These data include such information as

more than 90% of known germline APC mutations resulted in a truncated protein. Of these, 18% of the germline mutations occur at two mutation hot spot regions: codons 1061-1063 and 1309-1311. See the paragraph bridging pages 698, right column and page 699, left column. Bapat et al. indicate that the frequency of common and novel mutations in 202 families were published in 1994. See page 699, left column, last paragraph and reference number 17 on page 703. All these data are interpreted as historical data indicative of the frequency distribution of mutations relating to a disease, as recited in the instant claims. Bapat et al. also disclose APC mutation distributions in different age groups as previously (historically) disclosed by others. See Table 1 on page 700. The compilation of these data of mutation distributions in the APC gene and in different patient age groups from research in the past is interpreted as a history database. Bapat et al. disclose that for evaluating the cost of identifying germline APC mutations, mutation testing are done with patients in Gastrointestinal Cancer Registry using molecular diagnostic technologies in the authors' laboratory. There were 124 FAP families that have been screened using these mutation analysis and truncating mutations are identified in 92 families. See page 699. These data is interpreted as the new data indicative of the frequency distribution of mutations relating to a disease, as recited in the instant claims. At least one decision tree algorithm is used in cost comparison analysis of the mutation testing strategy versus clinical screening strategy including the baseline model and sensitivity model. See page 700, Fig. 1. The decision analysis is based on information about the new data (see page 699, right column). In the decision analysis, a threshold is set as a point at which the two strategies have equal costs. See page 701. The cost obtained by decision analysis reveals a cost value at 252, satisfying the threshold value at 851. See Table 4 on page 701. The costs for each test as determined by the decision analysis are also projected in Table 4. The comparison by Bapat et al. also reveals that genetic testing approach, i.e. mutation analysis, costs about one third to one thirteenth less than that of the conventional clinical strategy over a wide range of variables, which makes Bapat et al.

recommend that "on the basis of economic variables alone, molecular genetic testing was the method of choice." See page 702, left column.

As to the systems in claims 4-6, Bapat et al. disclose that their decision tree models are constructed and evaluated using the software program referred to as SMLTREE. Given that such a computer software was used, it would have been readily recognized by one skilled in the art that the computer using the software must have included an input device for receiving data, a computing environment, an output device and the software comprising the decision tree algorithm. Note that since claims 4-6 are drawn to systems comprising an input device "for receiving data" and an output device "for outputting data," the claims do not required actual actions of inputting data and outputting data.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bapat et al. (Gut, Vol 44, pages 698-703, 1999).

The claims are drawn to a computer readable medium comprising computer executable instructions for performing a process for determining an optimal test order. The process comprises receiving data, creating a database, receiving new data, applying a decision tree algorithm and generating a recommendation.

As set forth for claims 4-6 and 12-14 above, Bapat et al. disclose such a process. However, they do not explicitly disclose a computer readable medium comprising computer executable instructions for performing the process.

In *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), the court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplish the same result is not sufficient to distinguish over the prior art (see also *Manual of Patent Examining Procedure,* U.S. Trademark and Patent Office, section 2144.04, III).

In the instant case, the claimed invention merely makes the process of Bapat et al. as computer-implemented or automatic and indeed accomplishes the same result. It is thus not sufficient to distinguish over Bapat et al. Therefore, the claimed invention, i.e. the computer readable medium comprising instructions to execute a process would have been obvious to a person of ordinary skill in the art at the time the invention was made over the process disclosed by Bapat et al.

Furthermore, while Bapat et al. do not explicitly disclose such a computer medium comprising instructions for executing all the steps of the process as in claim 1, they do disclose that their decision tree models are constructed and evaluated using the software program referred to as SMLTREE. Thus they at least disclose a computer readable medium comprising instructions for executing at least steps c)-e) as in claim 1, i.e. the steps of receiving data, applying the decision tree algorithm and generating recommendation. Thus, the entire method of

Bapat et al. could be interpreted as semi-automatic. One of ordinary skill in the art would have been motivated to make it completely automatic by comprising instructions in the computer readable medium for executing the steps of a) and b) to take the obvious advantage of an fully automatic process, i.e. saving time and cost.

There would have been a reasonable expectation of success because the court held regarding software that "writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed." Fonar Corp., 107 F.3d at 1549, 41 USPQ2d at 1805.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of

the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.

Patent Examiner